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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/568,704

Filing Date: Feb 16, 2006

Appellant(s): Bortlik et al

Robert M. Barrett
For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed 9/29/2010 appealing from the Office Action mailed 5/27/2010.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments after Final

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 6,224,876

Kesharlal et al

5-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, and 9-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (line 1), 9 (line 3), 10 (line 3), and 11 (line 2) recite “natural lycopene concentrate”. The term “natural lycopene concentrate” in claims 1, and 9-11 is a relative term which renders the claim indefinite. The term “natural” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, on page 8 of the specification, Applicant recites “The supernatant is recovered and its

pH is adjusted to 7 with NaOH" (lines 5-10). Since NaOH does not exist in nature in tomato, it is not clear whether the product could still be called "natural lycopene concentrate".

Thus, the metes and bounds of claims 1, and 9-11 are rendered uncertain by the phrase "natural lycopene concentrate" in claims 1, and 9-11 because "natural" could be a relative term.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, and 9-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kesharlal et al (US 6,224,876).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/24/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Kesharlal et al teach fresh hard, good quality reddish colored "Desi Red" carrots with a smooth surface, excluding those that were found defective, were selected and washed thoroughly with water. The sorted and washed carrots (1.0 kg) were subjected to crushing in a fruit mill to

provide a comminution which was subjected to pressing through a filter press for the purpose of separating the pulp from the juice to provide a juice (ca. 600 ml) (thus water soluble at room temperature, thus the concentrate is extracted form a lycopene-containing material without using a solvent, thus a solid-liquid separation). To the juice, 3 g of adipic acid was added with stirring (thus not more than 10% organic acid). To the resulting mixture was added 60 g of sorbitol and the mixture was subjected to centrifuging to provide paste (ca. 17.2 g). The paste was dried under high vacuum. Pulverizing of the solid material and sieving gave the carotenoid powder (thus ingestible, thus in a powder form) of the invention (3.8 g) (col 7, Example 1). The composition of the product is given below. Composition per 100 g product from "Desi Red" carrots (Example 1): beta-Carotene 530 mg; alpha-Carotene 27 mg, Lycopene 700 mg (thus 7 mg/g; thus at least 1 mg of lycopene per g); Lutein/Xeaxanthin 15 mg; Total Carotenoids 3750 mg; Proteins 32.8 g (thus 32.8%); Carbohydrates 4 g; Phosphorus 647 mg; Lipids 15.3 g (thus 15.3%); Vitamin C 22 mg; Vitamin B1 5 mg; Vitamin B2 1 mg; Iron 95 mg; Zinc 1 mg; Manganese 1 mg; Magnesium 162 mg; Calcium 1.381 g; Potassium 1.99 g; Sodium 1.99 g; Total Minerals (Ash value) 6.87 g (col 8, 1st table). In Example 2, Kesharlal et al also teach the "Bangalore local" carrots were processed according the procedure described in Example 1. Composition per 100g product from "Bangalore local" carrots contain 30.3 g lipids (thus at least 30% lipid compounds), and protein 31.5 g (thus 31.5%). Even though Kesharlal et al do not explicitly teach not more than 30% protein, in Example 3, Kesharlal et al teach the protein range from different supplies contain 10-50% protein. Kesharlal et al further teach 5 participants sensitive to continuous exposure to sunlight and suffering from skin erythema on longer exposure were administered the tablets over a period of four weeks. Significant reduction of the

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symptoms induced by long exposure were observed (col 12, lines 20-25) (thus a cosmetic composition (that is taken orally) for slowing aging of the skin and/or to combat skin damage which may be caused by exposure to ultraviolet light). Kesharlal et al further teach the tablets (thus a composition which can be ingested orally, thus a dietary supplement) were prepared by blending nutrient-rich carotenoid powder with sucrose and Microcrystalline cellulose, granulating with Starch Gelatin paste, drying, lubricating with Talc, Magnesium stearate and Colloidal silicon dioxide followed by compression into tablet (col 10, lines 15-20).

Kesharlal et al do not explicitly teach a natural lycopene concentrate containing not more than 30% protein.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to vary the amount of the protein in a natural lycopene concentrate since in Example 3, Kesharlal et al teach different supplies contain 10-50% protein. Therefore, it would have been obvious for one of the ordinary skill in the art to choose a particular protein content carrot from different carrot species or supplier. Since Kesharlal et al yielded beneficial results for producing lycopene containing product, one of ordinary skill in the art would have been motivated to make and use the invention.

From the teachings of the references, it is apparent that one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

(10) Response to Argument

Appellant argues that "As is clearly stated in the specification, "[t]he aim of the present invention is to provide a 'natural' product with increased bioavailability, that is to say that the product has only been subjected to technological treatments which do not modify its native characteristics." See, specification, page 3, paragraph 7 (emphasis added). The specification further states that "the process of extraction according to the invention is simple, rapid and economical and at no time subject to the state of viability of the endoenzymes of the raw material." See, specification, page 4, paragraph 8. As such, the skilled artisan would immediately appreciate that a "natural" lycopene concentrate is a lycopene concentrate that has not been subjected to technological treatments that would modify its native characteristics. Indeed, the specification clearly defines a "natural" lycopene concentrate as a lycopene concentrate that "has only been subjected to technological treatments which do not modify its native characteristics." Thus, not only is the phrase "natural lycopene concentrate" explicitly defined in the specification, but the skilled artisan would immediately appreciate what it means to modify the native characteristics of a lycopene concentrate" (page 12, 3rd paragraph). Appellant also argues that "In contrast, Appellants submit that a "natural product" is, in fact, defined in the specification. As stated above, the specification clearly states that "[t]he aim of the present invention is to provide a 'natural' product with increased bioavailability, that is to say that the product has only been subjected to technological treatments which do not modify its native characteristics." See, specification, page 3, paragraph 7 (emphasis added). Thus, the skilled artisan would appreciate the meaning of "natural" lycopene based on the express definition of a "natural" product" (page 13, 2nd paragraph).

This is not found persuasive. As indicated in the final rejection, "natural" is a relative term, people might consider that only tomato concentrate going through squeezing or pressing procedure is considered as "natural", and most people would consider when "NaOH" is added to a tomato concentrate (see Specification, lines 5-10), it is not "natural", as a natural tomato doesn't contain NaOH solution. Therefore, the metes and bounds of claims 1, and 9-11 are rendered uncertain by the phrase "natural lycopene concentrate" in claims 1, and 9-11 because "natural" is a relative term which is relative to an unclear standard.

Appellant argues that "Further, the Manual for Patent Examining Procedures ("MPEP") and case law precedent have found time and again that an applicant for patent may be her own lexicographer. Indeed, the Federal Circuit has found that "[p]atent law allows the inventor to be his own lexicographer ... [T]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification. *United States v. Teletronics, Inc.*, 8 U.S.P.Q. 2d 1217, 1220 (Fed. Cir. 1988). As such, Appellants may define "natural" in any manner desired. "By statute... Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention." *In re Pilkington*, 162 U.S.P.Q. 145, 148 (C.C.P.A. 1996). Therefore, in contrast to the Examiner's suggestion, there exists no requirement for patentability that Appellants must define terms to mean what "most people" would expect the term to mean. Moreover, Appellants have chosen a definition of the term "natural" that Appellants submit corresponds with a skilled artisan's understanding of the term. Indeed, it seems logical that a "natural" product would not have been subject to technological treatments that would modify its native characteristics" (page

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13, 3rd paragraph). Appellant also argues that "Moreover, Appellants respectfully submit that it does not matter if the pH of a solution is adjusted to 7 with NaOH, as is suggested by the Examiner. See, final Office Action, pages 2-3. Instead, Appellants submit that when the claims are read in view of the specification, the skilled artisan would immediately appreciate that using NaOH to alkalinize a lycopene-containing composition, or acidifying a filtrate prior to centrifugation clearly does not change the native characteristics of the ultimate lycopene-containing composition because, as discussed above, the lycopene concentrate "has only been subjected to technological treatments which do not modify its native characteristics." As such, the skilled artisan would understand that the alkalinization and acidification steps described in the specification do not change that the lycopene concentrates are "natural."

This is not found persuasive. Because a naturally existing tomato juice is acidic in its pH value, then acidic is its native characteristic. By adding "NaOH" to neutralize its pH it seems to exactly "subject to technological treatments that would modify its native characteristics", which contradicts the definition of "natural" by Appellant's Specification. It is very unclear how there couldn't be a contradiction that makes the metes and bounds of what constitutes a "natural lycopene concentrate" as claimed. If "it does not matter if the pH of a solution is adjusted to 7 with NaOH", it makes it unclear what other native characteristics of the claimed concentrate could be manipulated by a technological means and still be considered as "natural". Therefore, the use of "natural" renders the claims vague and indefinite because it is unclear what is, and is not, excluded by the term as it relates to the claimed lycopene concentrate.

Regarding the 103 rejection, Appellant argues that “Appellants further submit that the skilled artisan would have no reason to modify *Kesharlal* to arrive at the present claims because *Kesharlal* teaches away from the present claims. As discussed above, independent Claims 1 and 10-11 recite, in part, natural lycopene concentrates comprising at least 1 mg of lycopene per g of the said concentrate, not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds. As such, the claims are directed to natural concentrates that cannot include more than 30% proteins” (page 16, 1st paragraph).

Appellant also argues that “For example, and as admitted by the Examiner, *Kesharlal* fails to disclose or suggest concentrates containing not more than 30% protein as required, in part, by the present claims. Indeed, since *Kesharlal* “teaches a protein range from about 10-50%,” *Kesharlal* clearly discloses that protein amounts in the range of 30-50% are acceptable. However, this is in direct contrast to the present claims that explicitly require “no more than 30% proteins.” As such, the disclosure of *Kesharlal* clearly teaches away from the present claims” (page 16, 3rd paragraph). Appellant further argues that “The Examiner goes further to state that “*Kesharlal* does not 'teach away' from the claimed invention, as it does not say 'more than 30% of the protein will not work.'" See, final Office Action, page 8, lines 15-16. However, Appellants respectfully disagree and submit that such an explicit disparagement is not required in order for a reference to teach away from a claimed invention. Indeed, the presence of 30-50% protein in the composition of *Kesharlal* is not merely the disclosure of an alternative embodiment. Rather, the presence of 30-50% protein in the compositions of *Kesharlal* teaches that such amounts of protein are not only acceptable, but also preferred. See, *Kesharlal*, Examples. In contrast, the present claims clearly require the opposite conclusion that more than 30% protein is not an

acceptable amount. As such, Appellants submit that the disclosure of *Kesharlal* clearly teaches away from the present claims.” (page 16, last paragraph bridging page 17).

This is not found persuasive. First of all, *Kesharlal* teaches every limitation of the claims, except “not more than 30% protein”. If *Kesharlal* teaches that part, it would have been a rejection under 35 USC 102, not under 35 USC 103. Secondly, *Kesharlal* teaches a protein range from about 10-50%, which overlaps with the claimed “not more than 30% protein”, and it would have been obvious for one of the ordinary skills in the art to choose any concentration from that range, including embodiments that are 30% protein or less and thus read on “not more than 30% protein”. As indicated by *Kesharlal*, different reddish varieties of carrots such as “Pusa Kesar” “Pusa Meghali”, “Desi Red” are available, and orange-colored varieties such as “Bangalore local” and “Ooty Hybrid” are available too (col 4, lines 44-48). Different varieties of carrots will have different nutrition profiles, and thus the protein levels among different varieties of carrots will vary too. It would have been obvious for one of the ordinary skills in the art to choose different protein levels from the taught range of 10-50%, picking ranges of protein concentrations of 10-30% or 30-50% according to the preference of the consumers which is well within the purview of the skilled artisan. Furthermore, *Kesharlal* does not “teach away” from the claimed invention, as it does not say, “more than 30% of the protein will not work”. Appellant argues that the cited reference teaches away from the claimed invention. According to MPEP 2123, "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” In re Gurley,

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27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have “relatively acceptable dimensional stability” and “some degree of flexibility,” but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant’s argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since “Gurley asserted no discovery beyond what was known in the art.” 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

For the other above mentioned reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Qiuwen Mi/

Primary Examiner, Art Unit 1655

October 19, 2010

Conferees:

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